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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,113	08/06/2003	Deborah Jean Hinten		9784

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EXAMINER

HENDERSON, MARK T

ART UNIT PAPER NUMBER

3722

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,113	HINTEN, DEBORAH JEAN	
	Examiner	Art Unit	
	Mark T Henderson	3722	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Faxing of Responses to Office Actions

In order to reduce pendency and avoid potential delays, TC 3700 is encouraging FAXing of responses to Office Actions directly into the Group at (703)872-9306. This practice may be used for filing papers which require a fee by applicants who authorize charges to a PTO deposit account. Please identify the examiner and art unit at the top of your cover sheet. Papers submitted via FAX into TC 3700 will be promptly forwarded to the examiner.

Drawings

1. New formal drawings are required in this application because the applicant has not properly labeled and distinguished which drawing is "Fig. 1" and "Fig. 2".

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Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

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- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Reference to a "Microfiche Appendix": See 37CFR 1.96(c) and MPEP § 608.05, if the application was filed before March 1, 2001. The total number of microfiche and the total number of frames should be specified. Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc and an incorporation by reference of the material on the compact disc.
- (e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

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- (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
- (2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In

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chemical cases it should point out in general terms the utility of the invention.

If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

No personal information should be given.

- (g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person

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skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

- (I) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(I)-(p).
- (j) Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims.

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(k) Drawings: See 37 CFR 1.81, 1.83-1.85, and MPEP § 608.02.

(l) Sequence Listing, if on paper: See 37 CFR 1.821-1.825.

2. The disclosure is objected to because of the following informalities:

Specification contains personal information which should not be disclosed in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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4. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, since it does not produce a useful, concrete and tangible result. Claim 1 is directed to a chart listing mere arrangements of printed matter, i.e., medical data. Mere arrangement of printed matter though seemingly a "manufacture," is rejected as not being within the statutory classes.

See *In re Miller*, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); *Ex parte Gwinn*, 112 USPQ 439 (Bd. App. 1955); and *In re Jones*, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967). See MPEP 706.03(a)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Tung et al (5,799,981).

Tung et al discloses in Fig. 1A-1C, a pharmaceutical log comprising a chart (Fig. 1) which displays possible side effects for everyone, Fig. 1C.

In regards to the log determining any possible over medication problems, life threatening bothersome side effects, possible law suits and deaths, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, the log of Tung et al is capable of determining any possible problems, effects, law suits and deaths.

Applicant's Response

The following consists of general information for the Applicant's benefit.

Unless the Office explicitly requests the return of a paper, all papers mailed to the

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Applicant are intended to be kept by the Applicant for his own records. The response must be signed by ALL applicants.

I. Amendments to the Specification

After March 1, 2001, all amendments to the specification, including the claims, must be made by replacement paragraph/section/claim in clean form (without underlining and bracketing) in order to eliminate (1) the need for the Office to enter changes to the text of application portions by handwriting in red ink, and (2) the presence of hard to scan brackets and underlining to improve the patent publishing process. This practice requires the applicant to provide a clean copy of an amended paragraph/section/claim together with a marked up version using applicant's choice of a marking system showing the changes being made which will aid the examiner. The marked up version must be based on the immediate previous version and indicate (by markings) how the previous version has been modified to produce the clean replacement paragraph(s), section(s), specification or claim(s) submitted in the current amendment. "Previous version" is

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defined as the version of record in the application as originally filed or from a previously entered amendment.

(1) Amendment by instruction to delete, replace, or add a paragraph.

Amendments to the

specification, other than the claims and listings provided for elsewhere, may be made by submitting:

(I) An instruction, which unambiguously identifies the location, to delete one or more paragraphs of the specification, replace a deleted paragraph with one or more replacement paragraphs, or add one or more paragraphs;

(ii) Any replacement or added paragraph(s) in clean form, that is, without markings to indicate the changes that have been made; and

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(iii) Another version of any replacement paragraph(s), on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of the paragraph(s). The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added paragraph or a deleted paragraph as it is sufficient to state that a particular paragraph has been added, or deleted.

(2) Amendment by replacement section. If the sections of the specification contain section

headings as provided in 37 CFR §§ 1.77(b), 1.154(b), or § 1.163(c),

amendments to the specification, other than the claims, may be made by submitting:

(I) A reference to the section heading along with an instruction to delete that section of the specification and to replace such deleted section with a replacement section;

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(ii) A replacement section in clean form, that is, without markings to indicate the changes that have been made; and

(iii) Another version of the replacement section, on one or more pages separate from the amendment, marked up to show all changes relative to the previous version of the section. The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system.

(3) Amendment by substitute specification . The specification, other than the claims, may also

be amended by submitting:

- (I) An instruction to replace the specification;
- (ii) A substitute specification in compliance with § 1.125(b); and
- (iii) Another version of the substitute specification, separate from the substitute specification, marked up to show all changes relative to the previous version of the specification.

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The changes may be shown by brackets (for deleted matter), or underlining (for added matter), or by any equivalent marking system.

An example of an amendment to the specification could appear as follows:

On page 16, line 12, change "effect" to --affect--.

On page 23, line 4, insert --bucket-- after "backhoe".

(Note: the inserted language is placed between double dashes.)

If a new specification is submitted, a marked up copy of the original specification is also required.

II. Amendments to the Drawings

Any amendment to the drawings modifying, deleting or inserting figures must be specifically requested in the amendment. Any changes must be shown in red-ink on the drawings. Any insertion of new figures must be set forth in the amendment and the specification must be amended in the Brief Description of the Drawings as well as in the Detailed Description of the Drawings sections in a manner as set forth above.

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III. Amendments to the Claims

All amendments to a claim must be presented in the form of a rewritten claim. Any rewriting of a claim will be construed as a direction to cancel the previous version of the claim. See *In re Byers*, 230 F.2d 451, 455, 109 USPQ 53, 55 (CCPA 1956)(amendment of a claim by inclusion of an additional limitation had exactly the same effect as if the claim as originally presented had been canceled and replaced by a new claim including that limitation). Any rewritten or newly added claim must be submitted in clean form, that is, with no markings to indicate the changes that have been made, and must be accompanied by a marked up version separate from the amendment using applicant's choice of marking system to indicate the changes being made. A parenthetical expression should follow the claim number indicating the status of the claim as amended or newly added, e.g., "amended," "twice amended," or "new," in both the clean version and the marked up version. A marked up version does not have to be supplied for any added claims or any canceled claims. If a marked up version is supplied to show changes made to amended claims, however, applicant should identify (in the marked up version) any added or canceled claims with a statement, such as, "Claim 6 has been

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canceled." A canceled claim can be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

Applicants may submit a clean version (with no markings) of all of the pending claims in one amendment paper. Applicants may wish to consolidate all previous versions of pending claims from a series of separate amendment papers into a single clean version in a single amendment paper. Providing this consolidation of claims in the file will be beneficial to both the Office and the applicant for patent printing purposes. When rewriting a claim in the clean set, the parenthetical expression, if any, from the claim to be rewritten should not appear in the clean set. Thus, the only time a parenthetical expression should appear in the clean set is when a claim is being amended. See MPEP § 714.13 for submitting a clean set of claims under 37 CFR 1.116 and MPEP § 714.16 for submitting a clean set under 37 CFR 1.312. See also MPEP § 714.22(a). It is recommended that the following format be used by applicants in complying with the revised amendment practice requirements. The amendment paper should include, in the following order:

- (A) a clean version of the amended (replacement) paragraph(s)/claim(s);
- (B) a remarks section (beginning on a separate sheet); and

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(C) a marked-up version (also beginning on a separate sheet) showing changes

and clearly identified as "Version with markings to show changes made."

The submission of a clean version of all pending claims shall be construed as directing the cancellation of all previous versions of any pending claims. A marked up version would only be needed for claims being changed by the current amendment (see 37 CFR 1.121(c)(1)(ii)). Any claim not accompanied by a marked up version will constitute an assertion that it has not been modified relative to the immediate prior version. Thus, if applicant is not making any amendments to the claims, but is merely presenting all pending claims in clean form, without any underlining and bracketing, a marked up version should not be submitted.

As an example, if a claim for a chair were originally written as follows:

1. A chair comprising a horizontal seat, a vertical back, and a plurality of vertical support members.

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An amended marked-up version of this claim might then be written as follows:

1. (Amended) A chair comprising a horizontal seat, a vertical back, and [a plurality of] four vertical [support members] legs attached to said seat.

In this example, the words "a plurality of" and "support members" have been deleted from the claim. The words --four-- and --legs attached to said seat-- have been inserted.

If the specification or drawings originally described the inclusion of four legs on the chair, the new limitation of "four legs" in the claim would not constitute new matter.

IV. Arguments

If an Office Action contains a rejection or objection to the claims, the Applicant **MUST** respond with arguments under the heading "Remarks", pointing out disagreements with the Examiner's contentions. The Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or patentably distinguish from them. The applicant must respond to

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every ground of rejection and objection set forth in the Office Action. For more details of the amendment process, the Applicant can refer to 37 Code of Federal Regulations Sections 1.118 - 1.121.

V. New Matter

As previously mentioned, no amendment to the specification, claims, or drawings may introduce new matter. "New matter" constitutes any material which meets the following criteria:

- a) It is added to the disclosure (either the specification, the claims, or the drawings) after the filing date of the application, and
- b) It contains new information which is neither included nor implied in the original version of the disclosure. This includes the addition of physical properties, new uses, etc.

VI. Period for Response

The three month shortened statutory period specified in the cover letter (form PTO-326) is the period of time in which the Applicant has to respond to every

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rejection and objection within this Office Action. The Applicant's response must be received within three months of the date listed on the cover letter, or the application will be held abandoned.

This period, however, may be extended up to a maximum of six months, with the appropriate fee payment.

VII. Certificate of Mailing

To ensure that the Applicant's response is considered timely filed, it is advisable to include a "Certificate of Mailing" on at least one page of the response. This "Certificate" should consist of the following statement:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: "Commissioner of Patents and Trademarks, Washington, D.C. 20231" on (date).

(signature)

This "Certificate" may appear anywhere on the page, and may be handwritten or typed. It MUST be signed by the person who actually deposits the paper with the Postal Service, and the date MUST be the actual date on which it is mailed.

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For the purpose of calculating extensions of time, the date shown on the certificate will be used as the date on which the paper was received by the Office, regardless of the date the Postal Service actually delivers the response. In this way, postal delays would not affect the extension-of-time fee.

Prior Art References

The prior art references listed in the attached PTO-892, but not used in a rejection of the claims, are cited for (their/its) structure. Shuffstall, Mayfield, and Barsky et al disclose similar pharmaceutical logs.

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark T. Henderson whose telephone number is (703)305-0189. The examiner can be reached on Monday - Friday from 7:30 AM to 3:45 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, A. L. Wellington, can be reached on (703) 308-2159. The fax number for TC 3700 is (703)-872-9302. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC 3700 receptionist whose telephone number is (703)308-1148.



MTH

September 24, 2004



A. L. WELLINGTON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700